

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants: Jay D. Kranzler and Srinivas G. Rao

Serial No.: Continuation of 10/028,547

Art Unit: Not Yet Assigned

Filed: July 18, 2003

Examiner: Not Yet Assigned

For: *METHODS OF TREATING FIBROMYALGIA SYNDROME, CHRONIC
FATIGUE SYNDROME AND PAIN*

Assistant Commissioner for Patents
Washington, D.C. 20231

INFORMATION DISCLOSURE STATEMENT

Sir:

Pursuant to 37 C.F.R. §1.56 and 37 C.F.R. §1.97, Applicants submit an Information Disclosure Statement, including four (4) pages of Form PTO-1449 and copies of ten (10) documents cited therein. Most of the documents cited below were cited by or submitted to the Patent Office in Application Serial No. 10/028,547, filed December 19, 2001, to which the present application claims priority. Pursuant to 37 C.F.R. §1.98(d), Applicants are not enclosing copies of these publications. Copies will be provided upon request, however. Copies of the newly cited documents, which are identified with an asterisk (*), are enclosed.

This Information Disclosure Statement is being filed under 37 C.F.R. § 1.97(b) prior to a first Office Action on the merits. It is believed that no fee is required with this submission. However, should a fee be required, the Commissioner is hereby authorized to charge any required fees to Deposit Account No. 50-1868.

U.S. Patents

<u>Number</u>	<u>Issue Date</u>	<u>Patentee</u>	<u>Class/Subclass</u>
5,621,142	04-15-1997	Mochizuki	564/164
4,478,836	10-23-1984	Mouzin	424/248.54
5,034,541	07-23-1991	Bigg	548/477
6,395,788	05-28-2002	Iglehart, III	514/654
6,441,038	08-27-2002	Loder, et al.	514/561

Foreign Documents

<u>Number</u>	<u>Publication Date</u>	<u>Patentee</u>	<u>Country</u>
*0 759 299	02-26-1997	Eli Lilly & Co.	EP
✓*2 752 732	03-06-1998	Pierre Fabre Medicament	FR
WO 95/22521	08-24-1995	Asahi Kasei Kabushiki Kaisha	PCT
WO 97/35574	10-02-1997	Pierre Fabre Medicament	PCT
*WO 97/35584	10-02-1997	Eli Lilly & Co.	PCT
WO 98/08495	03-05-1998	Pierre Fabre Medicament	PCT
WO 98/36744	08-27-1998	Pierre Fabre Medicament	PCT
*WO 99/59593	11-25-1999	Eli Lilly & Co.	PCT
*WO 00/32178	06-08-2000	Mueller	PCT
WO 01/26623	04-19-2001	Laxdale Ltd	PCT
*WO 02/053140	07-11-2002	Pharmacia & Upjohn Co.	PCT

Publications

ARDID, et al., "Antidepressants and pain," *La Lettre de Pharmacologue* 13: 8 (1993).

Cypress Bioscience, Inc., Investor Fact Sheet, August 2001.

DRYSON, "Venflaxine and fibromyalgia," *NZ Med. J.* 113(1105): 87 (2000).

*DWIGHT, et al., "An open clinical trial of venlafaxine treatment of fibromyalgia," *Psychosomatics* 39: 14-17 (1998).

GOODNICK, et al., "Psychotropic treatment of chronic fatigue syndrome and related disorders," *J. Clin. Psychiatry* 13-20 (1993).

MEDLINE, et al., "Treatment of chronic fatigue syndrome with sibutramine..." *PCT Int'l Appl.* 14 (09/28/2000).

NAGAOKA, et al., "Beneficial effects of a serotonin-noradrenaline reuptake inhibitor on fibromyalgia syndrome: a case report," *Med. Drug. J.* 37: 10 (2001).

*NINAN, "Use of venlafaxine in other psychiatric disorders," *Depression Anxiety* 12S: 1:90-94 (2000).

NOGUCHI, et al., "Open channel block of NMDA receptors by conformationally restricted analogs of milnacipran and their protective effect against NMDA-induced neurotoxicity," *Synapse* 31: 87-96 (1999).

*NUTT & JOHNSON, "Potential applications of venlafaxine," *Rev. Contemp. Pharmacother.* 9: 321-331 (1998).

*RAO, "The neuropharmacology of centrally-acting analgesic medications in fibromyalgia," *Rheum. Dis. Clin. N. Amer.* 28: 235-259 (2002).

SHUTO, et al., "(±)-Z-2-(Aminomethyl)-1-phenylcyclopropanecarboximide derivatives as a new prototype of NMDA receptor antagonists," *J. Med. Chem.* 38: 2964-2968 (1995).

SHUTO, et al., "(1S,2R)-1-(phenyl-2-[(s)-1-aminopropyl]-N,N-diethylcyclopropanecarboxamide (PPDC), a new class of NMDA-receptor antagonist: molecular design by a novel conformational restriction strategy," *Jpn. J. Pharmacol.* 85: 207-213 (2001).

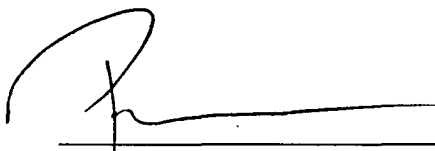
SHUTO, et al., "Synthesis and biological activity of conformationally restricted analogs of milnacipran: (1S,2R)-1-(phenyl-2-[(S)-1aminopropyl]-N,N-diethylcyclopropanecarboxamide, an efficient noncompetitive N-methyl-D-aspartic acid receptor antagonist," *J. Med. Chem.* 39: 4844-4852 (1996).

SHUTO, et al., "Synthesis and biological activity of conformationally restricted analogues of milnacipran: (1S,2R)-1-phenyl-2-[(r)-1-amino-2-propynyl]-N,N-diethylcyclopropane-carboximide is a novel class of NMDA receptor channel blocker," *J. Med. Chem.* 41: 3507-3514 (1998).

Remarks

This statement should not be interpreted as a representation that an exhaustive search has been conducted or that no better art exists. Moreover, Applicants invite the Examiner to make an independent evaluation of the cited art to determine its relevance to the subject matter of the present application. Applicants are of the opinion that their claims patentably distinguish over the art referred to herein, either alone or in combination.

Respectfully submitted,



Patrea L. Pabst
Reg. No. 31,284

Dated: July 18, 2003

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INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	Continuation of 10/028,547
				Filing Date	July 18, 2003
				First Named Inventor	Jay D. Kranzler
				Group Art Unit	
				Examiner Name	
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Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office. ³	Number ⁴	Kind Code ⁵ (if known)				
		EP	*0 759 299		Eli Lilly & Co.	02-26-1997		
		FR	*2 752 732		Pierre Fabre Medicament	03-06-1998		
		PCT	WO 95/22521		Asahi Kasei Kabushiki Kaisha	08-24-1995		
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		PCT	*WO 97/35584		Eli Lilly & Co.	10-02-1997		
		PCT	WO 98/08495		Pierre Fabre Medicament	03-05-1998		

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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
		ARDID, et al., "Antidepressants and pain," La Lettre de Pharmacologue 13: 8 (1993).	
		Cypress Bioscience, Inc., Investor Fact Sheet, August 2001.	
		DRYSON, "Venlafaxine and fibromyalgia," NZ Med. J. 113(1105): 87 (2000).	
		*DWIGHT, et al., "An open clinical trial of venlafaxine treatment of fibromyalgia," Psychosomatics 39: 14-17 (1998).	✓
		GOODNICK, et al., "Psychotropic treatment of chronic fatigue syndrome and related disorders," J. Clin. Psychiatry 13-20 (1993).	
		MEDLINE, et al., "Treatment of chronic fatigue syndrome with sibutramine..." PCT Int'l Appl. 14 (09/28/2000).	
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		*NINAN, "Use of venlafaxine in other psychiatric disorders," Depression Anxiety 12S: 1:90-94 (2000).	✓
		NOGUCHI, et al., "Open channel block of NMDA receptors by conformationally restricted analogs of milnacipran and their protective effect against NMDA-induced neurotoxicity," Synapse 31: 87-96 (1999).	
		*NUTT & JOHNSON, "Potential applications of venlafaxine," Rev. Contemp. Pharmacother. 9: 321-331 (1998).	✓

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Sheet	4	of	4
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OTHER ART -- NON PATENT LITERATURE DOCUMENTS			
Examiner's Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published	T ²
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